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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/985,742 12/04/92 COMAI

L. CGNE-62-1(1)
EXAMINER

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18M2

ART UNIT PAPER NUMBER

22

1804

DATE MAILED:

05/28/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 18 May 1993 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 20, 22-28, 30, 33-36, and 43 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 21, 29, 31-32, and 37-42 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 20, 22-28, 30, 33-36, and 43 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The finality of the rejection of the last Office action is is withdrawn in order to enter a new ground of rejection.

The rejection of claims 20-42 under 35 U.S.C. § 112, second paragraph, is is withdrawn in view of amended and cancelled claims.

The rejection of claims 20-42 under 35 U.S.C. § 112, first and second paragraphs, is is withdrawn in view of amended and cancelled claims.

The rejection of claim 41 under 35 USC § 112, first paragraph, for undue breadth is is withdrawn in view of cancelled claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 22-27, and 33-35 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by either Gowda et al or Wu et al.

Claims 20, 22-27, and 33-36 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Goldberg et al.

Applicant's arguments filed 25 November 1991 concerning the above rejections with respect to now cancelled claims 1-11 and 16-17 have been reconsidered but they are not deemed to be persuasive because the Sanger Declaration (Paper No. 7) is not sufficient. Rule 131 requires the signature of all inventors as

the declaration must show completion of the invention by all of the inventors.

5 The rejection of claims 39-40 under 35 U.S.C. § 102(b) as being anticipated by Shepherd et al where the sequence of interest is an FMV gene is withdrawn in view of cancelled claims.

10 The rejection of claims 20-21, 23-27, and 33-34 under 35 U.S.C. § 102(b) as being anticipated by Richins et al which disclosed cloned XbaI fragments joined in a 5' to 3' direction to β -galactosidase is withdrawn in view of amended claims.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

15 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that
20 the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same
30 person.

Claims 20, 22-28, 30, 33-36, and 43 are rejected under 35 U.S.C. § 103 as being unpatentable over Shah et al and Sanders et al taken with either Richins et al or Gowda et al or Wu et al or Goldberg et al.

35 The primary references disclosed all features of the present invention except for specifying FMV 34S instead of CaMV 35S as an alternative viral promoter. The secondary references disclosed the FMV 34S promoter which was analogous in structure and strong expression characteristics with the well-known CaMV 35S promoter
40 long used in recombinant constructs in transgenic plants. At the time this invention was made, it was obvious to one of ordinary

skill in the art to modify the primary references with the teachings of the secondary references in order to express genes of interest with yet another strong viral promoter with a reasonable expectation of success. Thus the invention as claimed was very clearly prima facie obvious as a whole over the prior art in the absence of clear and convincing evidence to the contrary.

Applicant's arguments filed 25 November 1991 concerning the above rejection with respect to now cancelled claims 1-19 have been reconsidered but they are not deemed to be persuasive because the Sanger Declaration (Paper No. 7) is not sufficient. Rule 131 requires the signature of all inventors as the declaration must show completion of the invention by all of the inventors.

Claims 20, 22-28, 30, and 33-36 remain rejected (claims 21, 29, 31-32, and 37-42 now cancelled) and new claim 43 is rejected under 35 U.S.C. § 103 as being unpatentable over Shah et al and Sanders et al taken with Richins et al and Shepherd et al as applied in the last office action and repeated herein.

Each of the primary references disclosed all features of the present invention (including constructs with genes of interest controlled by two different strong, constitutive promoters one of which was a CaMV 35S promoter) but did not identify FMV 34S as an alternative viral promoter. Richins et al disclosed the FMV 34S promoter sequence and taught that it was analogous to CaMV 35S in position, structure, and function and, likewise, expected to have similar strong expression characteristics. This was echoed by Shepherd et al which taught that FMV was as amenable to cloning manipulation as CaMV. Shepherd et al described the broad host range and high titer achievable with FMV in plant host cells and also compared CaMV and FMV promoters. At the time this invention was made, it was obvious to one of ordinary skill in the art to modify the primary references with the teachings of the secondary references in order to obtain high levels of expression of genes of interest in host plant cells with yet another strong viral promoter source. The extensive comparative analogy drawn with CaMV would have led one of ordinary skill in the art to have

5 reasonably expected to obtain high levels of constitutive expression with analogous FMV promoters. Thus the invention as claimed was very clearly prima facie obvious as a whole over the prior art in the absence of clear and convincing evidence to the contrary.

10 Applicant's arguments and the Sanger Declaration filed 18 May 1993 have been fully considered but they are not deemed to be persuasive. The facts and prior art considered in this rejection are not those of the cited caselaw. CaMV 35S was not the only plant viral promoter known and used at the time this invention was made. As noted in the prior office action (Paper No. 19), "promoter" was used in a non-standard way in this application to include the TATA box and the entire untranslated flanking region
15 which lies 5' of the TATA box. Applicant's remarks which focus on the TATA box and its sequence now suggest that the definition of "promoter" in the response has shifted from the definition of "promoter" that was the subject matter of this application. Such a shift will not be permitted as the rejection is based upon the
20 expanded definition of "promoter".

25 CaMV 35S was not the only plant viral promoter known and used at the time this invention was made. Furthermore, plant viral promoters do not exist in a vacuum; viral promoters and plant gene promoters were widely known and characterized in light of a vast background of basic knowledge about eucaryotic RNA polymerase II promoters. The TATA box is ubiquitous and is identified on the basis of consensus sequence. The CAAT box is not always present and is also identified by consensus sequence.

Regulatory elements which make up the "promoter" of any given gene occur throughout the 5' upstream region and typically were expected to be within about 1000 bases or so of the TATA box. A transcription start site is usually found about 20-25 bases to the 3' of the TATA box.

These features have nothing to do with promoter strength or with the teaching in the prior art that the promoter was expected to be analogous in strength to its CaMV 35S counterpart. The "sequence gazing" done by the prior art to locate the TATA box was the same "sequence gazing" that applicant did in locating the TATA box in this application. The teaching of the prior art was based upon a variety of factors.

Concern about titer is misplaced and applicant's position on the issue is unclear in that titer is said to be unrelated to promoter strength on the one hand and yet a reason to think that one strain would not have a strong promoter on the other hand. Discussion of gag is also misplaced; these are not retroviruses.

The prior art pointed to the claimed invention and taught that it was expected to be a strong promoter analogous to its counterpart in CaMV. Expectations of success do not have to be absolute only reasonable and applicant provides no basis for thinking that these expectations were not reasonable.

Serial No. 07/985742
Art Unit 1804

-7-

No claim was allowed.

Any inquiry concerning this communication should be directed
to P. Moody (nee Rhodes) at telephone number (703) 308-0196.

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PRM
P. Moody
May 26, 1993

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DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

David T. Fox

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